Citation:

Rosado JL, del R Arellano M, Montemayor K, García OP, Caamaño Mdel C. An increase of cereal intake as an approach to weight reduction in children is effective only when accompanied by nutrition education: a randomized controlled trial. *Nutr J.* 2008 Sep 10;7:28.

PubMed ID: 18783622

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

1. To determine if an increase in cereal intake by consuming ready to eat cereal (RTEC), among overweight or at risk of overweight children is an effective treatment to reduce excess body fat,
2. To determine if the inclusion of nutrition education program in addition to an increase in carbohydrate intake has an effect on body weight and body fat, and
3. To determine if an increase in RTEC intake alone or with a nutrition education program has an effect on plasma lipid profile.

Inclusion Criteria:

Children with Body Mass Index (BMI) for age > 85%, attending any of 6 elementary schools in Queretaro, Mexico, healthy and age 6 to 12 years.

Exclusion Criteria:

One of the 6 schools eligible to participate declined. Normal weight (<85% BMI for age) were not included in the study.

Description of Study Protocol:

Recruitment

Six elementary schools in Queretaro, Mexico were asked to participate in the study.

Of the 5 that agreed, 905 children were initially screened after parent approval.

Design: Randomized controlled trial

Blinding used

Treatment group assignment was done by computer generated random number list at a central office by

someone who did not have contact with the children or their parents.

Intervention

During the 12 week study,

- Group 1 consumed one serving RTEC at breakfast,
- Group 2 consumed two servings of RTEC; one at breakfast and one at dinner,
- Group 3 consumed one serving of RTEC and mother and child received nutrition education, and
- Group 4 received no intervention but was monitored in the same manner as other groups.

Statistical Analysis (Software SPSS, V.9.0)

- Within effects were carried out with a paired t test
- Between groups effect in lipids and anthropometry changes was observed with a one-way ANOVA to compare unadjusted changes and with a univariate general linear model adjusted for baseline value, gender and interactions
- Treatments' pairwise comparisons were tested with the least significant difference test
- Additionally, an ANOVA and a chi-square test were carried out to compare baseline age, anthropometry and gender of subjects included in the analysis versus children that had missing data and were not included in the analysis

Data Collection Summary:

Timing of Measurements

- Children recruited October to December 2002
- Study commenced January to June 2003
- Initial and final measurements were taken before and after the 12 week treatment period

Dependent Variables

- Weight change
- Body mass index change
- Body fat percentage change
- Effect on plasma lipids (cholesterol, triglycerides, HDL, LDL, VLDL)

Independent Variables

- Group 1 consumed one serving RTEC at breakfast,
- Group 2 consumed two servings of RTEC; one at breakfast and one at dinner,
- Group 3 consumed one serving of RTEC and mother and child received nutrition education, and
- Group 4 received no intervention but was monitored in the same manner as other groups.

Control Variables

- Baseline value
- Gender
- Interactions
- School random effect

Description of Actual Data Sample:

Initial N: 905 children screened, 256 overweight and risk for overweight accepted to participate, 178 completed study

Attrition (final N): 178 children (meets expected sample size with an alpha error of 0.05 and beta error of 0.2 to detect BMI changes). Of these, 129 also allowed blood testing.

Ethnicity: not specified

Age, Other Relevant Demographics and Anthropometrics:

	Group 1 (1 RTEC)	Group 2 (2 RTEC)	Group 3 (1 RTEC + Education)	Group 4 (Control)
Group, N	46	48	45	39
Male/Female (%)	56.4 / 43.6	40.5 / 59.5	47.5 / 52.5	51.6 / 48.4
Age (m)	110.3 ± 19.7	109.3 ± 18.9	107.8 ± 18.8	110.1 ± 18.9
BMI (kg/m^2)	23.7 ± 3.3	24.3 ± 3.7	23.8 ± 3.1	24.3 ± 3.1
Blood work, N	27	36	34	32
Cholesterol (mg/dL)	141.3 ± 31.3	140.6 ± 32.9	127.4 ± 23.3	138.8 ± 32.9
Triglycerides (mg/dL)	108.6 ± 45.2	132.2 ± 46.4	130.2 ± 47.7	125.1 ± 45.1

No statistically significant differences were found among groups at baseline.

Location: Mexico

Summary of Results:

Key Findings

There was a significant increase in body weight in the two RTEC groups and in the control group.

After 12 weeks of intervention only the children that received 33 ± 7 g of RTEC and nutrition education had significantly lower body weight [-1.01 (-1.69, -0.34), $P < 0.01$], lower BMI [-0.95 (-1.71, -0.20), $P < 0.01$], and lower total body fat [-0.71 (-1.71, 0.28), $P < 0.05$] compared with the control group.

This group also reduced BMI significantly compared to control (0.64 kg/m^2, $p<0.01$) and decreased total body fat (1.15 kg, $p<0.05$).

These children were also the only group to show significant reduction in triglycerides [-20.74 (-36.44, -5.05), $p<0.05$], increase in HDL [6.61 (2.15, 11.08), $p<0.01$] and small reduction in VLDL [-3.78 (-6.91, -0.64), $p<0.05$].

The groups that received 1 or 2 doses of RTEC alone were not significantly different to the control group.

Author Conclusion:

A strategy to increase RTEC consumption, as a source of carbohydrate, to reduce obesity in children is effective only when accompanied with a nutrition education program. The need for education could be extrapolated to other strategies intended for treatment of obesity.

Reviewer Comments:

Strength: participants were allowed to eat a variety of cereals to prevent taste fatigue

Weakness: cereals used were not high in fiber, no group was assigned a nutrition education only treatment for comparison

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Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes
Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes

3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	???
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	???
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes

10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes